IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS INTERNATIONAL GMBH, CEPHALON, LLC, and EAGLE PHARMACEUTICALS, INC.,	)	**Redacted - Public Version**
Plaintiffs,	)	C.A. No. 23-490-JLH **CONSOLIDATED**
v.	)	[redacted]
BENDARX USA CORP.,	)	
Defendant.	)	

STIPULATION AND [PROPOSED] ORDER TO EXTEND TIME

WHEREAS, the pursuant to the Scheduling Order, the deadline for completion of fact discovery is currently November 8, 2024;

WHEREAS, Defendant BendaRx USA Corp. ("BendaRx") has not yet received tentative approval from the U.S. Food & Drug Administration ("FDA") to market BendaRx's New Drug Application ("NDA") Product;

WHEREAS, [redacted] FDA sent BendaRx a Complete Response Letter recommending that, to resolve the deficiencies identified in the letter, BendaRx conduct additional clinical studies;

WHEREAS, BendaRx is currently conducting studies in response to FDA's Complete Response Letter;

WHEREAS, BendaRx anticipates submitting its response to FDA's Complete Response Letter [redacted];

[redacted]

[redacted]

WHEREAS, the parties wish to avoid burdening the Court with potential disputes about the approvability of BendaRx's NDA Product and further wish to avoid burdening the Court with the task of deciding a case that may prove unnecessary;

WHEREAS, the thirty-month stay is currently set to expire on November 5, 2025;

WHEREAS, Pursuant to LR 16.4, counsel have sent copies of this Stipulation to their respective clients;

NOW THEREFORE, the parties hereby stipulate and agree, subject to the approval of the Court, that the following deadlines are extended as follows:

Event	Current Deadline	Proposed Deadline
Fact Discovery Completed	November 8, 2024	April 18, 2025
Deadline to Join Parties, Amend/Supplement Pleadings	November 15, 2024	April 25, 2025
Plaintiffs Produce Final Infringement Contentions	November 22, 2024	May 30, 2025
Defendant Produces Final Invalidity Contentions	November 22, 2024	May 30, 2025
Opening Expert Reports Due	December 20, 2024	June 13, 2025
Responsive Expert Reports, Including Plaintiffs' Reports Relating to Objective Indicia of Non-Obviousness Due	January 31, 2025	August 8, 2025
Reply Expert Reports Due	February 28, 2025	September 5, 2025
Expert Discovery Completed	April 11, 2025	October 10, 2025

Deadline to File *Daubert* Motions	April 18, 2025	October 17, 2025
Final Proposed Pretrial Order Due	May 5, 2025	Two weeks before trial
Pretrial Conference	May 12, 2025	One week before trial
Trial	May 19, 2025	December 2025
Thirty-Month Stay Deadline	November 5, 2025	November 5, 2025
Expiration of U.S. Pat. Nos. 8,791,270; 8,609,863; and 8,895,756 (including pediatric exclusivity)	N/A	July 12, 2026

[redacted] BendaRx further stipulates and agrees that it will notify Plaintiffs within seven days of responding to FDA's Complete Notice Letter and will further notify Plaintiffs within seven days of receiving FDA's classification and response;

Within fourteen days of Plaintiffs' receiving the classification, the parties shall meet and confer and apprise the Court as to whether they believe that any further action is required;

BendaRx further stipulates and agrees that it will produce all correspondence to or from FDA regarding BendaRx's NDA or NDA Product no later than seven days of sending or receiving the same;

This Stipulation is without prejudice to the parties' individual rights to seek further relief from the Court, as warranted by the issues discussed above.

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SO ORDERED this ____ day of November, 2024.

_____
Hon. Jennifer L. Hall

CERTIFICATE OF SERVICE

I hereby certify that on November 4, 2024, this document was served on the persons listed below in the manner indicated:

BY EMAIL

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